

### REMARKS

Claims 1-20 are in this application and are presented for consideration. By this application, Applicant has amended claim 1. New claims 9-20 have been added.

The Office Action states that should Applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted.

Applicant has attached a certified English translation of the foreign application.

Claims 1-8 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claim of copending Application No. 10/513,316.

Application No. 10/513,316 fails to disclose a surgical implant as claimed. Application No. 10/513,316 merely refers to a flat mesh implant, i.e a hernia mesh. However, the present invention relates to a surgical implant, which comprises a film layer of a thin, bioresorbable, smooth film that is located beneath a stabilizing layer, which is in the form of a reinforcing mesh. Application No. 10/513,316 provides no teaching or suggestion for a flat surgical implant that comprises a film layer and a reinforcing mesh as featured in the present invention. As such, it is Applicant's position that the two applications refer to patentably distinct inventions. Accordingly, Applicant respectfully requests that the Examiner remove the provisional rejection.

Claims 1-8 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention.

Applicant has amended the claims paying close attention to the Examiner's remarks. Specifically, Applicant has amended claim 1 to remove the phrase "in particular". It is Applicant's position that the claims as now presented are clear and fully comply with the requirements of the statute. Accordingly, Applicant respectfully requests that the Examiner remove the indefiniteness rejection in view of the claims as now presented.

Claim 8 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the Office Action states that the specification does not give any examples of a hemostatic or hemostyptic agent.

Applicant respectfully disagrees. A person of ordinary skill in the art would understand that a hemostatic agent relates to any agent that helps to stop bleeding. Any agent which promotes hemostasis can be incorporated into the hemostyptic layer on the outside of the flat implant. A person of skill in the ordinary art can readily select such an agent to be incorporated into the layer. As such, it is Applicant's position that claim 8 contains subject matter which is sufficiently described in the specification such that one skilled in the art can make and/or use the invention. Accordingly, Applicant respectfully requests that the Examiner remove the rejection.

Claims 1-5 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Devereux et al. (U.S. 5,092,884) in view of Melican et al. (U.S. 2002/0120348).

The present invention relates to a surgical implant that is provided in operated areas for post-operative repair in pericardial, peritoneal or gynaecological surgery. The surgical implant

comprises at least one film layer that includes a thin, bioresorbable and smooth film. The implant also includes a reinforcing mesh of plastic material that defines a stabilizing layer. The stabilizing layer is joined to the film layer and is provided with a metal-containing, biocompatible, continuous coating. This advantageously provides support for the operated area as a result of the stabilizing layer and prevents tissue-to-tissue adhesions in the operated area. The prior art as a whole fails to disclose such features and such tissue-to-tissue adhesion prevention advantages.

Devereux et al. fails to teach and fails to suggest the combination of a surgical implant that comprises a film layer of a bioresorbable film and a stabilizing layer connected to the film layer wherein the stabilizing layer is composed of plastic material that is completely coated with a metal-containing, biocompatible continuous coating. At most, Devereux et al. discloses a surgical composite that consists of a non-absorbable, biocompatible woven fiber mesh that is laminated between two films of a bioabsorbable polymer. However, Devereux et al. provides no teaching or suggestion for a metal-containing coating that is applied to a plastic material of a stabilizing layer such that the coating covers the entire plastic material of the stabilizing layer as noted in the Office Action. This is a completely different approach than that of the present invention. The fact that Devereux et al. discloses that no metal coating is applied to the woven fiber mesh is a significant disadvantage because a woven fiber mesh without any metal coating does not provide any support for the operated area and does not prevent tissue-to-tissue adhesions in the operated area. This is a significant departure from the present invention. As such, the prior art as a whole does not establish a prima facie case of

obviousness as the prior art as a whole does not teach or suggest each and every feature of the claimed combination.

The Office Action relies on the teachings of Melican et al. to disclose a surgical implant with a reinforcement material that is covered in a metallic coating.

Melican et al. fails to provide any teaching or suggestion for applying a coating to a reinforcing mesh as featured in the present invention. Melican et al. merely discloses a reinforced tissue implant that consists of at least one layer of a bioabsorbable polymeric foam and a reinforcement component that is preferably bioabsorbable. However, Melican et al. does not recognize the problems of applying a metal-containing coating to a surgical flat implant that comprises a film layer of a woven fiber mesh as featured in Devereux et al. Instead of being concerned with applying a metal-containing coating as featured in the present invention, Melican et al. discloses a thick foam structure that has a thickness of 2 to 3 mm wherein the 60 ml of foam forming solution is poured into a mold of a base area of  $15.3 \times 15.3 \text{ cm}^2$  to make up to  $234 \text{ cm}^2$  of foam structure. In this mold, the foam forming solution of Melican et al. makes up to a layer of 2.6 mm which differs from the thickness of the film layer of the present invention by a factor of 50 to 130. A person of skill would not look to the teachings of Melican et al. in view of Devereux et al. since Melican et al. does not provide any teaching or suggestion of applying a metal-coating to a thin layer of woven fiber mesh as featured in Devereux et al. As such, the prior art as a whole takes a completely different approach and fails to establish a prima facie case of obviousness.

Melican et al. does not teach and does not suggest the combination of applying a metal

coating to a stabilizing layer that is in the form of a reinforcing mesh of plastic material as claimed. The Office Action takes the position that paragraphs [0050] and [0051] of Melican et al. disclose a reinforcement material 13 that is covered in a metallic coating 12. Applicant respectfully disagrees with this interpretation of paragraphs [0050] and [0051] of Melican et al. Paragraphs [0050] and [0051] of Melican et al. must be given a fair reading for what they teach and suggest. Paragraphs [0050] and [0051] of Melican et al. only disclose non-bioabsorbable materials, which include titanium and titanium alloys, are added as additional solids to a polymer-solvent system for forming the foam structure. However, there is no teaching or suggestion in paragraphs [0050] and [0051] of Melican et al. that the non-bioabsorbable materials are used to coat a reinforcing mesh of plastic material as claimed. Melican et al. clearly discloses that the added solids, which include titanium and titanium alloys, are particles having an average diameter of about 50 to 500 microns and are present in an amount from about 1 to 50 volume percentage of the total volume of the particle and polymer-solvent mixture. This is a completely different approach than that of the present invention. Instead of using the titanium to coat the reinforcement material as featured in the present invention, Melican et al. directs a person of ordinary skill in the art to dispersing small particles in a foam structure such that the particles do not form a continuous coating as recited in the claimed combination. As such, the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature of the claimed combination. Accordingly, Applicant respectfully requests that the Examiner favorably consider claim 1 as now presented and all claims that depend thereon.

The references as a whole fail to provide any teaching or suggestion for the features recited in claims 2 and 3. The Office Action takes the position that it would have been obvious to make the coating less than 2 micrometers thick and to provide the formula of  $Ti_aO_bC_c$  as claimed. Applicant respectfully disagrees. The references must provide some teaching or suggestion for the features claimed. No such teaching or suggestion exists in either Devereux et al. or Melican et al. that would direct a person of ordinary skill in the art to the thickness or the composition of the metal-coating of the present invention. The thickness of the present invention is a significant feature of the claimed combination because it allows the implant to be flexible and lightweight so that the implant can be easily handled and placed into a surgical area. The composition of the present invention is also of significance because it advantageously provides a composition that can be safely placed within a living body without the material endangering the health of the subject. Devereux et al. and Melican et al. do not provide such handling and safety advantages since none of the references disclose the features of claims 2 and 3. As such, all claims define over the prior art as a whole.

Claims 6 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Devereux et al. in view of Melican et al., further in view of Lichtenstein et al. (U.S. 5,593,441). Claim 8 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Devereux et al. in view of Melican et al., further in view of Tormala et al. (U.S. 6,319,264).

All of these rejections are based on the interpretation of Devereux et al. and Melican et al. as teaching a stabilizing layer that is coated with a metal-containing coating. A fair reading of the Devereux et al. and Melican et al. references indicates that neither reference

discloses coating a reinforcing mesh of plastic material with a metal-containing coating as claimed. The references as a whole clearly do not direct a person of ordinary skill in the art towards the invention as claimed. Accordingly, reconsideration of these rejections is requested.

Applicant has added new claims 9-20. New independent claims 9 and 17 provide for similar features as found in claim 1, but further highlight that the reinforcing mesh of plastic material is in direct contact with the tissue operated area. New dependent claims 10-16 and 18-20 have been added to further clarify the features of the invention. Applicant respectfully requests that the Examiner favorably consider new claims 9-20 as presented.

Favorable consideration on the merits is requested.

Respectfully submitted  
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Attached: Certified English translation of the foreign application  
Petition For One Month Extension of Time

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SHOULD ANY OTHER FEE BE REQUIRED, THE PATENT AND TRADEMARK OFFICE  
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